Backgrounder

FSIS Pathogen Reduction/HACCP Proposal

SUMMARY

The Food Safety and Inspection Service (FSIS) is pursuing a broad, long term science-based strategy to improve the safety of meat and poultry products and better protect public health.

The strategy will address food safety issues from the farm to the table, including proposed requirements for all federally inspected meat and poultry plants to reduce pathogenic microorganisms that can cause foodborne illness. The strategy is based on the philosophy of prevention embodied in HACCP (Hazard Analysis and Critical Control Points), a science-based system for producing safe food.

The regulatory proposal would (1) target pathogens that cause foodborne illness; (2) strengthen industry responsibility to produce safe food; and (3) focus inspection and plant activities on prevention objectives.

The proposal addresses three major areas:

Near-term initiatives

FSIS is proposing that:

- All plants develop and use written standard operating procedures covering plant sanitation.
- Slaughter plants use at least one antimicrobial treatment on all carcasses.
- All finished carcasses and parts be chilled promptly after slaughter and be kept cool.

These requirements would have to be implemented within 90 days from the date of publication of the final rule and would remain in effect at least until a Hazard Analysis and Critical Control Points (HACCP) system is implemented.

Proposed Interim Targets for Pathogen Reduction and Microbial Testing

Under the proposal, FSIS would establish interim targets for pathogen reduction and require daily microbial testing in slaughter plants to determine whether targets are being met or remedial measures are necessary. Raw products would be tested for *Salmonella*, a representative pathogen, and establishments would be required to achieve targeted reductions in the incidence of *Salmonella* in relation to the current national baseline incidence. Microbiological testing would be required to begin in 90 days and tracking of test results would begin 6 months after the final rule is published. Compliance with the interim targets would be determined by using a moving sum statistical procedure that focuses on a specific number of days within a production process.

Hazard Analysis and Critical Control Points (HACCP)

All plants would be required to develop, adopt, and implement Hazard Analysis and Critical Control Points (HACCP), a system of preventive controls designed to improve the safety of products. HACCP would be implemented during the three years following the publication of the final rule. FSIS expects the near-term initiatives and microbial testing requirements to provide the foundation for the later adoption of HACCP by plants.

Implementation Costs

FSIS estimates the total implementation cost of its proposed requirements to the meat and poultry industry at $733.5 million, or an average of $244.5 million per year. Yearly public health benefits from reduced foodborne illness costs, including medical care and lost work time, would range from $990 million to $3.7 billion. The increased cost to consumers is estimated at slightly more than two tenths of a cent per pound.

Comments

The proposed USDA HACCP/Pathogen Reduction rule was published in the February 3 Federal Register. Comments on the proposal should be submitted to Diane Moore, Docket Clerk, Room 3171 South Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington DC 20250. Comments will be accepted through July 5.

June 1995

U.S. Department of Agriculture
Food Safety & Inspection Service

BACKGROUND

Current FSIS regulatory requirements and inspection procedures contribute to the FSIS mission of ensuring that meat and poultry products are safe, wholesome, and accurately labeled. More than 7,400 FSIS inspectors are present in 6,200 slaughter and processing plants to ensure that diseased animals and birds do not enter the food supply and that sanitation and other requirements are met. Inspectors also monitor the meat and poultry supply for violative levels of chemical residues.

Despite the successes of the current program, there is a critical gap in its ability to protect public health. The current system largely focuses on organoleptic (sensory) inspection, which was appropriate when the first major meat inspection law was passed in 1906. At that time, animal diseases were the major concern, and invisible hazards such as pathogenic microorganisms and drug residues had not yet attracted the attention of regulatory agencies. Since that time, changes have been made in the inspection program to reflect changes in the production of meat and poultry and to increase the efficiency of inspection. However, the current program still is inadequate to detect hazards such as pathogenic microorganisms that can cause foodborne illness. In short, it does not include integration of systematic process control into the production process to make meat and poultry as safe as possible.

While precise data on the incidence of illness associated with meat and poultry products is limited, it is clear that foodborne illness is a public health problem in the United States. Data from varied sources suggest that foodborne pathogens account for up to 7 million cases of foodborne illness each year, and up to 7,000 deaths. Of these, nearly 5 million cases of illness and more than 4,000 deaths may be associated with meat and poultry products.

Microbiological surveys of meat and poultry products conducted over the past several decades show the frequency of pathogenic microorganisms in cooked, ready-to-eat meat and poultry products to be relatively low. The frequency of pathogenic microorganisms in raw products has been greater and varies from pathogen to pathogen and from species to species.

Even when the incidence of contamination is relatively low, the public health threat can be serious. An example is the outbreak of foodborne illness that occurred in several western states in early 1993. The outbreak was attributed to undercooked hamburgers contaminated with *E. coli* 0157:H7 that were served at a chain of fast food restaurants. A study by FSIS completed in 1990 found the prevalence of *E. coli* 0157:H7 in raw beef to be only 0.1 percent. Nevertheless, this particular outbreak led to hundreds of cases of illness and four deaths. Although the Department of Agriculture's review of the outbreak revealed that the incident was not caused by a failure in the current inspection system, it concluded that the system as it exists is deficient because it does not adequately address the risk of microbial contamination.

This conclusion has been supported by many external studies conducted during the past decade. The National Academy of Sciences, the General Accounting Office, the National Advisory Committee on Microbiological Criteria for Foods, industry, producers and consumer groups have called for change in the current inspection system to better address microbial pathogens and make it more prevention-oriented.

FSIS Strategy

- Stimulate improvement in food safety practices by setting public health-oriented targets, guidelines, or standards that all plants must meet.
- Clearly define the minimum requirements all plants must meet to produce safe meat and poultry and ensure that plants are accountable for meeting them.
- Make meat and poultry plants responsible for microbial testing of their products to ensure proper process control and verify achievement of microbial limits.
- Foster scientific and technological innovation within the meat and poultry industry by removing any unnecessary regulatory obstacles to innovation.
- Build the principle of prevention into the operations of meat and poultry plants.
- Focus inspection on prevention objectives.
- Approach the food safety mission broadly and consider potential hazards that arise throughout the food production and delivery system, including before animals enter FSIS-inspected plants and after meat and poultry products leave those plants.

THE PROPOSAL

Near-Term Initiatives

- **Sanitation Standard Operating Procedures (SOPs)**

Insanitary conditions during the production of meat and poultry products increase the likelihood that pathogenic bacteria will contaminate the finished product. At the same time, poor sanitation is the most frequently observed problem in meat and poultry plants.

FSIS is proposing to require all plants to establish written SOPs for sanitation and maintain a system of records to document adherence to the procedures. The proposal does not change existing basic sanitation requirements found in the regulations or guidance contained in the FSIS Sanitation Handbook. Rather, the written sanitation SOPs would describe the specific activities plant management has determined are necessary to maintain good sanitation in a specific plant. Examples of specific practices that might be included in an SOP include pre-operational microbiological testing, disinfection of equipment prior to start up, proper hand washing between each carcass during skinning and evisceration, and cleaning cattle prior to slaughter.

Sanitation SOPs are intended to clarify that sanitation is industry's responsibility. They would make it easier for FSIS inspectors to perform their proper role of verifying that plant management is carrying out its sanitation responsibilities.

- **Antimicrobial treatments**

The proposed regulation would require that slaughtering plants apply at least one antimicrobial treatment to livestock and poultry carcasses before chilling or cooling. FSIS recognizes that this is not a complete solution to the problem of pathogenic microorganisms but, rather, is one part of a strategy to reduce pathogens.

For the purposes of this regulation, FSIS would approve specific antimicrobial treatments when data are available demonstrating that they are safe and effective and do not adulterate the product. The following are available antimicrobial treatments that FSIS tentatively concludes could satisfy its proposed requirements for a mandatory antimicrobial treatment: hot water; lactic, acetic, and citric acid solution sprays; trisodium phosphate; and chlorinated water. The Agency encourages the development of new antimicrobial procedures and will work with those who have developed and want to evaluate processing techniques designed to enhance product safety.

Antimicrobial treatments will not be allowed to substitute for careful sanitary dressing procedures. This new proposed requirement would not change the current FSIS policy regarding removal of physical contaminants from meat and poultry carcasses. The proposal clarifies that there is no tolerance for feces on poultry carcasses.

- **Time/Temperature Controls**

Rapidly cooling carcasses is one means of preventing the multiplication of pathogenic bacteria. FSIS is proposing that appropriate time/temperature controls for handling raw products, which many plants follow voluntarily based on prevailing industry standards, become mandatory.

Plants would be required to cool the surface of meat carcasses to 50° F or below within 5 hours and to 40° F or below within 24 hours from the time that carcasses exit the slaughter floor. In addition, carcasses and meat products would be required to be maintained at 40° F or below during handling, holding, and shipping.

Current poultry regulations already require that all poultry slaughtered and eviscerated be chilled immediately after processing so that the internal temperature is reduced to 40° F or below within a time period appropriate for the size of the carcass. Eviscerated poultry to be shipped must be maintained at 40° F or below, with certain exceptions. FSIS is proposing to amend the poultry regulations to include provisions for alternative time/temperature requirements, to mandate corrective actions when time/temperature controls fail, and to eliminate other provisions inconsistent with those being proposed for meat.

The proposed time/temperature cooling requirements for meat are equivalent to those in effect and being proposed for poultry in terms of their public health benefits and are readily attainable under current commercial conditions.

Plants would be required to develop, implement, and file a written plan for meeting the time and temperature requirements. Inspection personnel would verify that the written plan is being followed and would measure temperatures at various control points and compare them with those measured and recorded by the plant.

Products that are not chilled quickly enough, or that have been held at temperatures exceeding 40° F, would be required to be further processed to kill pathogens or be condemned.

Interim Targets for Pathogen Reduction and Microbial Testing

FSIS believes that the production of raw meat and poultry with an incidence of *Salmonella* below the current national incidence level is readily achievable with available technology and production methods. FSIS is proposing that all plants should be required to control their processes to achieve microbial targets below the national incidence level, and is therefore proposing interim targets for pathogen reduction in slaughter plants.

Under the proposal, plants would be required to sample and test representative products daily for the presence of *Salmonella*. FSIS would identify a national baseline incidence of *Salmonella* contamination for each major species and for ground meat and poultry. FSIS is proposing that within two years following the publication of the final rule, or within some other period specified by FSIS, all plants reduce contamination below the baseline, perhaps by some specified percentage. FSIS is interested in comments on what that percentage should be.

This is an initial step toward measurable reductions in microbial contamination and a first step toward the eventual incorporation of microbial testing as an integral part of process control and verification in plants operating under the HACCP approach. FSIS intends to work toward setting more definitive targets, guidelines, or standards, including the possible identification of levels of specific pathogens that pose a safety concern and the use of those levels for regulatory purposes. Even as the scientific basis for such standards develops, however, FSIS believes that significant reductions in the risk of foodborne illness can be achieved by requiring compliance with interim targets for pathogen reduction.

Salmonella was selected as the target pathogen because it is the leading cause of foodborne illness, it is present on virtually all raw food products, and it can easily be recovered from a variety of products. Reductions in *Salmonella* should also result in reductions of other human pathogens.

Each plant would be required to develop a written protocol, available for review by the inspector in charge, outlining specimen collection and handling.

The results would be entered into a moving sum process control table or chart, which provides immediate feedback on the effectiveness of the control system.

Plants that are not achieving the established targets for pathogen reduction within the period specified by FSIS would be required to take corrective action under FSIS supervision to improve process control to achieve the target.

Hazard Analysis and Critical Control Points (HACCP) Systems

FSIS is proposing that federally inspected meat and poultry plants adopt HACCP systems to provide documentation that their processes are in control and producing safe products. The HACCP approach is a preventive system of process control that is widely recognized by scientific authorities and international organizations and is used in the food industry to produce product in compliance with health and safety requirements.

Implementation of HACCP would clarify that the industry, not the inspection service, is responsible for producing safe meat and poultry products. With HACCP in place, FSIS would verify that the plant is controlling its processes and consistently producing products that comply with food safety requirements.

HACCP systems would cover those critical control points (CCP's) that affect product safety, as opposed to those related to economic adulteration and quality. A HACCP plan would be required for each type of processing activity carried out by the plant. FSIS would not approve HACCP plans in advance but would evaluate their effectiveness as part of the inspection process.

Plants would be required to develop HACCP plans based on the seven principles articulated by the National Advisory Committee on Microbiological Criteria for Foods:

(1) Conduct a hazard analysis;

(2) Identify the CCP's in the process;

(3) Establish critical limits for preventive measures associated with each identified CCP;

(4) Establish CCP monitoring requirements;

(5) Establish corrective action;

(6) Establish effective recordkeeping procedures; and

(7) Establish procedures for verifying that the HACCP system is working correctly.

Implementation would be phased in, based on the type of production process. It is proposed that implementation for processes associated with the greatest public health risk would begin 12 months after publication of the final rule. Implementation would be complete 36 months after publication of the final rule. Small establishments, which FSIS is proposing to define as those with an annual production valued at or below $2.5 million, would be permitted 36 months from the date of publication of the final rule to start their HACCP plans, regardless of the processes they carry out.

Food Safety from Farm to Table

The proposed regulations address product safety only within the plant environment. The Agency recognizes that ensuring food safety requires taking steps throughout the chain of production, processing, distribution, and sale to prevent hazards and reduce the risk of foodborne illness. To minimize the growth of pathogens once a product leaves the plant, FSIS is announcing its intent to initiate rulemaking with the Food and Drug Administration (FDA) to establish Federal standards for the safe transportation of foods. FSIS will also work with FDA to ensure food safety at the retail level by encouraging States to adopt and enforce consistent, science-based standards.

Although animal production food safety is not the subject of this regulatory proposal, FSIS also will work with animal producers and others to develop and implement food safety measures that can be taken on the farm and before animals enter the slaughter facility to reduce the risk of harmful contamination of meat and poultry products.

In addition, the Agency will continue its comprehensive food handler education programs to inform the public and those who prepare and serve food to the public on how to properly handle, prepare, and store meat and poultry products to minimize the growth of foodborne pathogens.

Health-Based Standards for Pathogenic Microorganisms

The proposed requirement that plants achieve a certain reduction in the incidence of *Salmonella* is an initial step toward articulating an acceptable level of food safety performance. The broader task of identifying levels of specific pathogens that pose a threat to public health is complex. FSIS intends to hold one or more public meetings to explore this and other topics with interested parties and intends to work closely with government and public health agencies, academia, industry, and consumer groups to develop the scientific basis for microbial risk assessment and health-based performance standards for pathogenic microorganisms.

Technology Development

Because the development and proper use of technology can contribute significantly to improving the safety of the food supply, FSIS is encouraging technology development in several ways. First, by setting public health standards, the Agency believes it is providing a heightened incentive to take innovative steps to improve food safety. Second, FSIS will review its policies and procedures governing the review and approval of in-plant technologies to simplify them as much as possible, while ensuring that safety and efficacy are not compromised. Third, FSIS will focus its own limited technology development resources on tools that can assist the Agency in detecting and evaluating food safety hazards and on research that requires a long-term commitment.

FSIS Inspection Roles

FSIS must consider the future roles of its inspection force. FSIS intends to work closely with the bargaining unit and employee organizations in formulating its plan for inspection under HACCP. FSIS must consider a number of issues, including

(1) what additional tasks FSIS inspectors should be performing under HACCP,

(2) what the role of FSIS inspectors should be in ensuring that Federal standards are met during transportation and at the retail level, and

(3) what new inspection tools and techniques are needed in a regulatory environment where greater responsibility for safety is being placed on industry.

Administration Food Safety Initiatives

These initiatives build on a number of important steps already undertaken by the Administration to strengthen and update the Federal inspection program for meat and poultry products. They include:

(1) the elevation of food safety to a sub-Cabinet-level responsibility within the Department of Agriculture,

(2) development of pathogen reduction legislation to target microbial pathogens in meat and poultry products and reduce the risks of foodborne illness,

(3) declaration of *E. coli* 0157:H7 in raw ground beef to be an illegal adulterant and initiation of a sampling program for raw ground beef,

(4) streamlined approval of antimicrobial treatments to help the beef industry move faster to install new technologies to reduce pathogens;

(5) initiation of unannounced reviews in 1,000 meat and poultry plants to enforce inspection requirements,

(6) implementation of mandatory safe handling instructions on labels of meat and poultry products, and

(7) increased funding for food safety research.

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